



[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-day comment request

Iwin: Navigating your Path to Well-Being.

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute on Drug Abuse (NIDA), the National Institutes of Health, has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the Federal Register on March 1, 2016, page 10640 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute on Drug Abuse (NIDA), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

DIRECT COMMENTS TO OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-

6974, Attention: NIH Desk Officer.

COMMENT DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact*: Dr. Belinda Sims, Health Scientist, DESPR, PRB, National Institute on Drug Abuse

6001 Executive Boulevard Room 5153, MSC 9589 Bethesda, Maryland 20892-9589 .- toll-free number (301) 402-1533 or E-mail your request, including your address to: bsims@nida.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

PROPOSED COLLECTION: Iwin: Navigating your Path to Well-Being, 0925-NEW, National Institute on Drug Abuse (NIDA,) National Institutes of Health (NIH).

Need and Use of Information Collection:

The overarching objective of this proposal is to conduct a randomized trial to evaluate the effectiveness of the Individual Well-Being Navigator (Iwin) mobile application, a substance abuse prevention and well-being enhancement program designed specifically for military personnel. Iwin provides an innovative, tailored mobile application using best practices in behavior change science and innovative technology to

assist military personnel in preventing substance abuse and enhancing well-being by providing them with the most appropriate intervention content at the right time. It integrates Transtheoretical Model of Behavior Change based tailoring, SMS messaging, stage of change matched activities, and engaging game-like features in a cutting edge multiple behavior change program. The first year of this project will focus on the completion of development and beta testing of the app. In year 2, the efficacy of the Iwin program will be determined by tests of statistical significance indicating that participants in the Treatment condition had lower scores on an index of substance use and other behavioral risks than the control group at 6 and 9 month follow-up. The overall design is a 2 group (treatment and control group) by 3 Occasions with repeated measures across occasions. Once shown to be effective, the Iwin program will assist organizations that serve military personnel to meet the directives of both the DoD and CJCS indicating that prevention programs be evidence based, evaluated by the specified populations and address full Total Force Fitness paradigm rather than a single behavior.

OMB approval is requested for 1 year. There are no capital, operating, and/or maintenance costs. The total estimated annualized burden hours are 1,760.

Estimated Annualized Burden Hours

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Time Per Response (in hours)	Total Annual Burden Hour
Screening (Attachment 3)		1,624	1	10/60	271

Baseline (Attachment 4)	Military Personnel	812	1	45/60	609
Follow-up Outcome Assessments (6 and 9 month) (Attachment 5)			2	30/60	812
Consent Form (Attachment 1)			1	5/60	68
Total		2,436	4872		1,760

Dated: May 28, 2016.

Genevieve R. deAlmeida

Project Clearance Liaison

NIDA, NIH

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